

PATIENT INFORMATION
TEMIXYS (Teh-mix-is)
(lamivudine and tenofovir disoproxil fumarate)
tablets

Read this Patient Information before you start taking TEMIXYS and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about TEMIXYS?

TEMIXYS can cause serious side effects, including:

- **Worsening of hepatitis B virus infection.** Your healthcare provider will test you for HBV and HIV before starting treatment with TEMIXYS. If you have Human Immunodeficiency Virus type 1 (HIV-1) and hepatitis B virus (HBV) infection, your HBV may get worse (flare-up) if you stop taking TEMIXYS. A “flare-up” is when your HBV infection suddenly returns in a worse way than before. Your healthcare provider will test you for HBV infection before you start treatment with TEMIXYS.
 - **Do not** run out of TEMIXYS. Refill your prescription or talk to your healthcare provider before your TEMIXYS is all gone.
 - **Do not** stop taking TEMIXYS without first talking to your healthcare provider.
 - If you stop taking TEMIXYS, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking TEMIXYS.

For more information about side effects, see “What are the possible side effects of TEMIXYS?”

What is TEMIXYS?

TEMIXYS is a prescription medicine that is used in combination with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in adults and children weighing at least 77 pounds (35 kg). HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

TEMIXYS contains the prescription medicines lamivudine and tenofovir disoproxil fumarate.

Do not take TEMIXYS if you are allergic to lamivudine, tenofovir disoproxil fumarate, or any of the ingredients in TEMIXYS. See the end of this Patient Information leaflet for a complete list of ingredients in TEMIXYS.

What should I tell my healthcare provider before taking TEMIXYS?

Before you take TEMIXYS, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems, including hepatitis B or C virus infection.
- have kidney problems, including end-stage renal disease (ESRD) that requires dialysis.
- have bone problems, including a history of bone fractures.
- are pregnant or plan to become pregnant. It is not known if TEMIXYS may harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with TEMIXYS.

Pregnancy Registry. There is a pregnancy registry for women who take TEMIXYS during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take TEMIXYS.
 - **Do not** breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Some medicines interact with TEMIXYS. TEMIXYS may affect the way other medicines work, and other medicines may affect how TEMIXYS works. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with TEMIXYS.
- Do not start a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take TEMIXYS with other medicines.

You should not take TEMIXYS if you also take:

- adefovir (HEPSERA®)

How should I take TEMIXYS?

- Take TEMIXYS exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking TEMIXYS without first talking with your healthcare provider. Stay under the care of a healthcare provider during treatment with TEMIXYS.
- Take TEMIXYS at the same time every day.
- Take TEMIXYS 1 time each day by mouth, with or without food.
- **Do not** miss a dose of TEMIXYS. If you miss a dose of TEMIXYS, take it as soon as you remember. If it is almost time for your next dose of TEMIXYS, do not take the missed dose. Take the next dose of TEMIXYS at your regular time.
- Do not take 2 doses at the same time or take more TEMIXYS than prescribed.
- Do not run out of TEMIXYS. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.
- If you take too much TEMIXYS, call your local poison control center or go right away to the nearest hospital emergency room.

What should I avoid while taking TEMIXYS?

You should avoid taking medicines that contain sorbitol during treatment with TEMIXYS.

What are the possible side effects of TEMIXYS?

TEMIXYS may cause serious side effects, including:

- **See “What is the most important information I should know about TEMIXYS?”**
- **New or worse kidney problems, including kidney failure.** Your healthcare provider may do blood and urine tests to check your kidneys before and during treatment with TEMIXYS. Tell your healthcare provider if you get signs and symptoms of kidney problems, including bone pain that does not go away or worsening bone pain, pain in your arms, hands, legs or feet, broken (fractured) bones, muscle pain or weakness.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when an HIV-1 infected person start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- **Bone problems** can happen in some children or adults who take TEMIXYS. Bone problems include bone pain, softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones or your child’s bones. Tell your healthcare provider if you have any bone pain, pain in your hands or feet, or muscle pain or weakness during treatment with TEMIXYS.
- **Too much lactic acid in your blood (lactic acidosis).** Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
- **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark “tea-colored” urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.
- **Use with interferon and ribavirin-based regimens.** Worsening of liver disease that has caused death has happened in people infected with HIV-1 and hepatitis C virus who were taking antiretroviral medicines for HIV-1 and were also being treated for hepatitis C with interferon alfa with or without ribavirin. If you are taking TEMIXYS and interferon with or without ribavirin, tell your healthcare provider if you have any new symptoms.
- **Risk of inflammation of the pancreas (pancreatitis).** Children may be at risk for developing pancreatitis during treatment with TEMIXYS if they:
 - have taken nucleoside analogue medicines in the past
 - have a history of pancreatitis
 - have other risk factors for pancreatitis

Call your healthcare provider right away if your child develops signs and symptoms of pancreatitis including severe upper stomach-area pain, with or without nausea and vomiting. Your healthcare provider may tell you to stop giving TEMIXYS to your child if their symptoms and blood test results show that your child may have pancreatitis.

The most common side effects of TEMIXYS include:

- rash
- headache
- pain
- diarrhea
- depression

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of TEMIXYS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TEMIXYS?

- Store TEMIXYS tablets below 86°F (30°C).
- Keep TEMIXYS in the original bottle.
- Keep the bottle of TEMIXYS tightly closed. The bottle contains a desiccant that helps to keep the tablets dry. Do not remove or eat the desiccant.
- **Do not** use TEMIXYS if the seal over the bottle opening is broken or missing.

Keep TEMIXYS and all medicines out of the reach of children.

General information about the safe and effective use of TEMIXYS.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TEMIXYS for a condition for which it was not prescribed. Do not give TEMIXYS to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about TEMIXYS that is written for health professionals.

A vaccine is available to protect people at risk for becoming infected with HBV. You can ask your healthcare provider for information about this vaccine.

What are the ingredients in TEMIXYS?

Active ingredient: lamivudine and tenofovir disoproxil fumarate

Inactive ingredients: cellactose 80 (lactose monohydrate and powdered cellulose), colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, and magnesium stearate

Tablet film-coating: hypromellose, polyethylene glycol, and titanium dioxide

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For more information, go to [CELLTRION WEBSITE](#) or call 1-844-837-6511.